



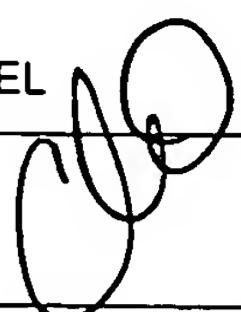
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/655,941	09/05/2003	Michael Lebner	0156-2003US02	7019
7590	06/09/2004		EXAMINER	
Kevin M. Farrell Pierce Atwood Suite 350 One New Hampshire Avenue Portsmouth, NH 03801			LEWIS, KIM M	
			ART UNIT	PAPER NUMBER
			3743	
				DATE MAILED: 06/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Interview Summary	Application No.	Applicant(s)
	10/655,941	LEBNER, MICHAEL 
	Examiner Kim M. Lewis	Art Unit 3743

All participants (applicant, applicant's representative, PTO personnel):

- (1) Kim M. Lewis (examiner). (3) Michael Lebner (applicant).
 (2) Kevin Farrel (attorney). (4) _____.

Date of Interview: 27 May 2004.

Type: a) Telephonic b) Video Conference
 c) Personal [copy given to: 1) applicant 2) applicant's representative]

Exhibit shown or demonstration conducted: d) Yes e) No.

If Yes, brief description: Applicant demonstrated his invention and also presented the examiner with a CD showing the basic application of the closure devices.

Claim(s) discussed: 42 and 43.

Identification of prior art discussed: U.S. Patent No. 5,263,970 ("Prellar").

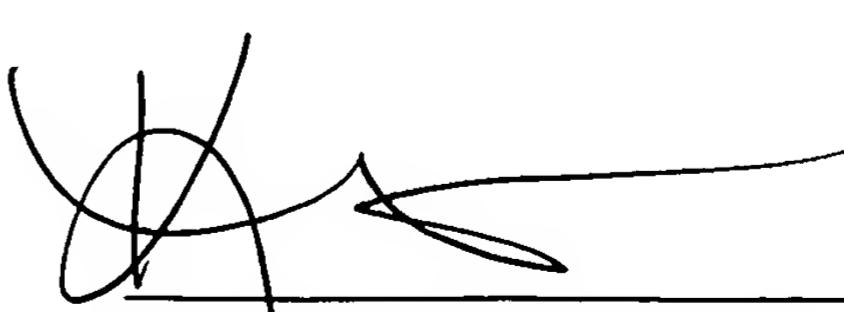
Agreement with respect to the claims f) was reached. g) was not reached. h) N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: See Continuation Sheet.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN ONE MONTH FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.


Examiner's signature, if required

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record

A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.

All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:

- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

- 1) A brief description of the nature of any exhibit shown or any demonstration conducted,
- 2) an identification of the claims discussed,
- 3) an identification of the specific prior art discussed,
- 4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
- 5) a brief identification of the general thrust of the principal arguments presented to the examiner,
(The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
- 6) a general indication of any other pertinent matters discussed, and
- 7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

Continuation of Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments:

First, applicant's attorney stated that the office action mailed 5/17/04 indicated that claims 46 and 53 are objected, but would be allowable if rewritten in independent form. Applicant's attorney presented a draft amendment in which the subject matter of claim 46 was added to independent claim 42 and the subject matter of claim 53 was added to claim 48. The examiner indicated that the amendments placed claims 42, 48 and any claims depending therefrom in condition for allowance.

Next, applicant and applicant's attorney demonstrated the device in order to show "lateral adjustment", a feature not taught or suggested by Prellar. After the demonstration, the examiner clearly understood how Prellar did not teach the demonstrated feature. However, the examiner pointed out that the phrase "lateral adjustment" was not present in the claims. Applicant's attorney indicated that the specification would be checked for proper claim language and that either a dependent or independent claim would be added to the claims to bring out this feature.

Next, applicant gave a brief discussion on component devices and how Prellar differed from component devices. Note attached pages 1 and 2.

Components Devices

The adhesive film based wound closure patents as we see it are divided into two groups:

1. The **component devices** (the better devices), and
2. All others closure devices.

The Component Device main feature:

The component devices have separate and distinct initial component parts that are linked or interlaced to each other, but not directly attached to each other. This is the most important feature as every wound is different. These devices have independent parts that can be attached separately and independently of the placement of the other part.

The Component Device categories and related patents include:

Four Component Patents: Roomi & Peterson (Four parts used to secure wound)

Three Component Patents: Owen Flynn & Peterson (Three Parts used to secure wound)

Two Component Patent: Lebner/ClozeX – (Two parts used to secure wound)

The Component Device common features:

1. They have independently moving initial components to apply on each wound edge
2. They have a distinct wound edge
3. They do not allow adhesive to get on or in the wound
4. They can close a wound and provide some lateral adjustment
5. The wound is open during the closure process providing clear visibility of the wound for alignment, and better access to wound for easier drainage and after closure easier inspection
6. They do not occlude the wound allowing easy flow of exudates, “openness to air” and application of dressing such as bacitracin.

Preller

The Preller device is not a component device and does not have even one of the characteristics. It has numerous deficiencies that would lead to fatal flaws in practical use.

The Preller device does not have wound edges or independent ends to apply. Basically you would apply the entire adhesive bottom of the device over the wound area. The possibility of **adhesive touching the inside tissue matter** and perhaps adhering to it is fatal flaw # 1.

The almond shape of the typical wound (surface view) requires a closure device to somehow move the center portion of the almond more than the ends. Preller only displays side views of a wound Fig 3 to 8 which does not address this closure requirement. If you examine Fig 3 to 8 only one slice of the wound is pictured. Preller cannot demonstrate how this works because it **cannot close the different gap widths along the same wound**. Fatal flaw #2

Figure 5 shows the closed wound with the attaching pads line up exactly on the landing pads and the skin pulled to the middle. This may happen that way, but rarely. What if there is a narrower gap? You may only have to pull the edges slightly. What about a wider gap? There is **limited flexibility to close the wound edges to varying degrees** as would be required from varying wound gap. Fatal Flaw #3.

Preller at best allows only for a straight-pull/tension closure. It **cannot provide any lateral adjustment/adjustment parallel to the wound**. Fatal flaw #4

Preller **does not allow for clear visibility** along the wound edge. See Figure 2. The wound area is covered throughout. Wounds closes to a center area which must be visible to the clinician. Preller's film is also bent 180deg over along the most critical line. Even with the clearest film the refraction through the bend would not be clear. The visibility problem is compounded because of the risk of blood and other exudates that can't readily escape because the wound is occluded. The exudates that can't drain could attach on the adhesive bottom as the wound is closed further blocking the view. Poor visibility during closing is fatal flaw # 5

The problem with occluding the wound during and after closure is also significant. There are two theories of healing. The dry theorists who want the wound open to air during healing. Preller does not do this. The wet theorists want to apply a dressing (like bacitracin) after the closure to keep the wound site moist and prevent infection. Preller does not accommodate this need either. The occlusion does not leave the wound open for subsequent minor treatment. Occluding the wound is fatal flaw #6

CLAIMS

42. (Amended) A method for closing a wound or incision comprising the steps of:
- a) providing a bandage for closing said wound or incision, the bandage comprising:
 - i) a first component having adhesive on a lower surface and a plurality of first elongated connectors extending from one edge thereof in a first direction, the plurality of first elongated connectors having adhesive on a surface for attaching the first elongated connectors to the second component of step a)ii);
 - ii) a second component having adhesive on a lower surface and at least one second elongated connector extending from one edge thereof in a second direction generally opposite to said first direction, the at least one second elongated connector having adhesive on a surface for attaching the at least one second elongated connector to the first component of step a)i);
 - b) attaching said lower surface of said first component to a patient's skin along a first side of said wound or incision;
 - c) attaching said lower surface of said second component to the patient's skin along a second side of said wound or incision;
 - d) aligning the edges of the first and second components in a direction parallel to their edges and closing the wound or incision;
 - e) fixing the first and second components relative to one another by:
 - i) attaching said first elongated connectors to said second component; and
 - ii) attaching said at least one second elongated connector to said first component.
43. (Original) The method of Claim 42 wherein the elongated connectors are sufficiently spaced-apart to facilitate adjustment of the first component relative to

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the second component for alignment of the edge of the first component with the edge of the second component.

44. (Original) The method of Claim 42 further comprising the steps of:
 - a) providing a first pulling element joined to said first elongated connectors;
 - b) providing a second pulling element joined to said at least one second elongated connector; and
 - c) pulling on each of said pulling elements to align said first and second components so as to close the wound or incision.
45. (Original) The method of Claim 44 further comprising the steps of:
 - a) removing said first pulling element from said first elongated connectors; and
 - b) removing said second pulling element from said at least one elongated connector.
46. (Cancelled) The method of Claim 42 wherein said bandage further comprises adhesive applied to a surface of each of said elongated connectors and wherein said adhesive attaches said first elongated connectors to said second component and attaches said at least one elongated connector to said first component.
47. (Original) The method of claim 45 wherein two or more elongated connectors are attached to said second component.
48. (Amended) A two-component bandage for closing a wound or incision comprising:
 - a) a first component having adhesive on a lower surface and a plurality of first elongated connectors extending from one edge thereof in a first direction, the plurality of first elongated connectors having adhesive on a surface for attaching the first elongated connectors to the second component of step b); and

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- b) a second component having adhesive on a lower surface and at least one second elongated connector extending from one edge thereof in a second direction generally opposite to the first direction, the at least one second elongated connector having adhesive on a surface for attaching the at least one second elongated connector to the first component of step a); and
- c) ~~means for attaching said first elongated connectors to the second component and means for attaching said at least one elongated connector to the first component;~~

wherein the elongated connectors are sufficiently spaced-apart to facilitate adjustment of the first component relative to the second component for alignment of the edge of the first component with the edge of the second component.

49. (Original) The bandage of Claim 48 wherein said first and second elongated connectors are interleaved.
50. (Original) The bandage of Claim 48 wherein there are two or more of said elongated connectors extending from said one edge of second component.
51. (Original) The bandage of Claim 48 further comprising a first pulling element joined to said first elongated connectors and a second pulling element joined to said at least one second elongated connector.
52. (Cancelled) The bandage of Claim 48 wherein the means for attaching of step c) is adhesive.
53. (Cancelled) The bandage of Claim 52 wherein the adhesive is applied to the lower surface of the elongated connectors.